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Atty. Dkt. No. 041457-0633

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: **Juan Mantelle et al.**

Title: **TRANSDERMAL COMPOSITIONS CONTAINING LOW MOLECULAR WEIGHT DRUGS WHICH ARE LIQUID AT ROOM TEMPERATURES**

Appl. No.: **09/986,945**

Filing Date: **11/13/2001**

Examiner: **Retford O. Berko**

Art Unit: **1618**

PRE-APPEAL BRIEF REQUEST FOR REVIEW

Mail Stop AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Applicants' arguments for review in support of the Pre-Appeal Brief Request submitted herewith are set forth below.

REMARKS

The rejection of Claims 1-21 as unpatentable under 35 USC § 103 over the combination of USPN 5,656,286 (Miranda et al.), USPN 5,474,783 (Miranda et al) and USPN 5,230,898 (Horstmann et al.) is presented for review. The omission of one or more essential elements required for a prima facie rejection and clear errors in the rejection are outlined below.

A. Lack Of Elements For Prima Facie Case

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, the prior art references must teach or suggest all of the claim limitations. Second, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally

available to one of ordinary skill in the art, to modify the references and combine their teachings. Third, there must be a reasonable expectation of success in achieving the invention. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

The present case at least lacks motivation to combine the references in the manner asserted and a reasonable expectation that the asserted combination would successfully achieve the present invention. This is apparent from the fact that each of the cited references focuses on a problem different from that addressed by the present invention.

The present invention addresses the tendency of low molecular weight drugs that are liquid at room temperature to plasticize polymer matrices, thereby making it difficult to formulate suitable transdermal patches comprising such drugs. This problem is noted in, for example, EP 0 887 075. The present invention addresses this problem by providing a blend that includes (i) a low molecular weight drug that is liquid at room temperature and (ii) a high shear resistant acrylic-based polymer. This problem is not even addressed by the cited references, which are each directed to solving different problems.

The '286 patent discloses polymer compositions comprising polyvinylpyrrolidone, which compositions are shown to be useful to prevent drug crystallization without affecting the rate of drug delivery. The '783 patent discloses a method of adjusting saturation concentration of a drug in a transdermal polymer composition comprising mixing polymers with different solubility parameters. Finally, the '898 patent discloses a transdermal therapeutic system with a specific arrangement of layers.

While the rejection cherry-picks specific elements of these prior art compositions and combines them in an attempt to arrive at the present invention, there is no motivation in these references or elsewhere that would lead the skilled artisan to choose selected elements from each

composition and combine them in the manner asserted. This is particularly so because none of the references are directed to the problem addressed by the present invention, but instead are each directed to solving different problems. Where only the present invention teaches the advantages of using high shear resistant acrylic-based polymers in order to address problems observed with low molecular weight drugs, the obviousness rejection is improper and should be withdrawn.

"The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination." MPEP § 2143.01 (citations omitted). Here, where the claimed references do not teach or suggest the desirability of the claimed combination, the obviousness rejection is improper. See *Ex parte Levengood*, 28 USPQ2d 1300 (BPAI 1993) (reversing an obviousness rejection because the prior art evinced no understanding in the art that would have motivated the skilled artisan to make the claimed invention). Indeed, the references of record are silent on the benefits of using a high shear resistant acrylic-based polymer in combination with drugs which are low molecular weight and liquid at or about room temperatures, as presently claimed. Thus, the rejection stems from impermissible hindsight guided only by the teachings of the instant application, and therefore should be withdrawn.

1. Clear Error In Rejection

At pages 5-6, the Final Office Action asserts that the '286 patent discloses the use of polymers "having shear resistance of 100 and above at 8lbs/sq in at 72 degrees F." As examples, the Office Action lists polymethylacrylate (col. 8, Table 1A), Bio-PSA X-7-4503, and Duro-Tak 80-1196. However, these polymers lack the recited characteristics. The '286 patent is silent on the shear resistance of the polymethylacrylate. Bio-PSA X-7-4503 is not acrylic-based but instead is silicone-based. Finally, Duro-Tak 80-1196 has a shear resistance of only about 15 hrs. at 8 lbs. per square inch at 72°F. Thus, the cited polymers do not have the characteristics of the polymers recited in the instant claims, and therefore do not support the obviousness rejection.

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In view of the foregoing and Applicants' other arguments of record, Applicants respectfully urge reconsideration and withdrawal of the §103 rejection, and an early notice of allowability.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicants hereby petition for such extension under 37 C.F.R. § 1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

Date September 2, 2005

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PRE-APPEAL BRIEF REQUEST FOR REVIEW

Docket Number (Optional): 041457/0633

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to "Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" [37 CFR 1.8(a)]

on _____

Signature _____

Typed or printed name _____

Application Number	Filed
09/986,945	November 13, 2001

First Named Inventor: Juan Manteâle et al.

Art Unit	Examiner
1618	Retford O. Berko

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).
Note: No more than five (5) pages may be provided.

I am the

☐ applicant/inventor.

☐ assignee of record of the entire interest.
See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed.
(Form PTO/SB/96)

☒ attorney or agent of record.
Registration number 37,288

☐ attorney or agent acting under 37 CFR 1.34.
Registration number if acting under 37 CFR 1.34 _____

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Typed or printed name

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Telephone number

September 2, 2005
Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required.
Submit multiple forms if more than one signature is required, see below*.

☒ *Total of 1 forms are submitted.

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